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NewLink Genetics Corporation Reports First Quarter 2012 Financial Results

AMES, Iowa, May 10, 2012 (GLOBE NEWSWIRE) -- NewLink Genetics Corporation (Nasdaq:NLNK), a biopharmaceutical company focused on discovering, developing and commercializing cancer therapeutics, today reported consolidated financial results for the first quarter of 2012, and provided an update on the progress of its clinical development programs.

"During the first quarter of 2012 we continued to advance our pivotal trial in pancreatic cancer and are also moving forward on a number of other HyperAcute immunotherapy development programs including those to treat melanoma and lung and kidney cancers," commented Dr. Charles Link, Chairman and Chief Executive Officer of NewLink. "We also made strides in our IDO pathway inhibitor program and are looking forward to presenting new data for a number of these programs at both DDW and ASCO. We believe that the receipt of patent allowances in both of our core programs will also facilitate our business development activities."

First quarter 2012 Financial Results

- | Cash, cash equivalents and certificates of deposit totaled \$35.8 million at March 31, 2012.
- | Total grant revenues for first quarter 2012 were \$471,000 compared with \$604,000 for first quarter 2011. Grant revenues will vary depending on the level of research funded under grants as well as changes in the overhead rates and profit factors agreed to under the grants. The decrease in revenue was due to reduced research by BPS under various Department of Defense contracts and National Institutes of Health grants.
- | Research and development (R&D) expense for first quarter 2012 was \$3.8 million compared with \$3.2 million for first quarter 2011. The increase was primarily due to increases in personnel-related expenses and clinical trial expense.
- | General and administrative (G&A) expense for first quarter 2012 was \$1.5 million compared with \$1.3 million for first quarter 2011. The increase was primarily due to increases in personnel-related expenses.
- | Net loss for first quarter 2012 was \$4.8 million or \$.23 per common share (based on 20.6 million weighted average shares outstanding), compared with \$3.9 million, or \$1.07 per common share, for first quarter 2011 (based on 3.6 million weighted average shares outstanding). The difference in the number of weighted average shares outstanding primarily resulted from NewLink's initial public offering in November 2011, as well as the conversion of all preferred stock to common stock in connection with the initial public offering.

Financial Guidance

NewLink is maintaining its financial guidance and continues to expect to end 2012 with about \$20 million in cash, cash equivalents and marketable securities. NewLink continues to anticipate that this capital should allow it to fund its operations through 2013 based on its current operating plans.

2012 Key Accomplishments to Date

- | Continued to advance our HyperAcute Pancreas Phase 3 clinical trial. Enrollment is matching our anticipated levels and we continue to expect to complete enrollment before the end of 2013. We still expect that our first interval look will occur at the end of 2012 or early 2013. Data from the HyperAcute Pancreas Phase 2 clinical trial will be presented at both the 53rd Annual Meeting of the American Gastroenterological Association in conjunction with Digestive Disease Week (DDW) on May 22, 2012 and the 2012 American Society of Clinical Oncology (ASCO) Annual meeting on June 4, 2012.
- | Studies with our IDO pathway inhibitor product candidate in combination with a dendritic cell vaccine or Taxotere continue and we anticipate data from these studies will be presented at ASCO in June, 2012.
- | Entered into a settlement agreement with the Iowa Economic Development Authority ("IEDA") as the successor organization to the Iowa Department of Economic Development. Under the terms of the settlement agreement we agreed to pay a 0.5% royalty on future product sales up to a cap of \$6.8 million in exchange for IEDA's release of our job creation and project expenditure obligations and IEDA's release of the security interest in substantially all of our assets.
- | The Japan Patent Office issued a notice of allowance for a patent entitled "Antitumor Vaccination Using Allogeneic Tumor Cells Expressing Alpha (1,3)-Galactosyltransferase," which contains broad pharmaceutical composition claims covering NewLink's HyperAcute products for the treatment of cancer. NewLink holds exclusive rights to the allowed application as well as to previously issued counterpart patents in the United States, Canada, Mexico, and Europe.

- | The United States Patent & Trademark Office (USPTO) allowed broad claims to oral pharmaceutical compositions comprising 1-methyl-D-tryptophan (D-1MT) (US Serial No. 12/175,538) and also to oral pharmaceutical compositions comprising 1-methyl-DL-tryptophan (US Serial No. 11/603,291). The company holds exclusive rights to the allowed applications.
- | We converted our letter of intent with the National Cancer Institute into a cooperative research and development agreement (CRADA).

Upcoming Activities

NewLink expects to present at the following investor conferences:

- | Jefferies 2012 Global Healthcare Conference, June 4-7, in New York City, NY.
- | 32nd Annual Canaccord Global Growth Conference, August 14-16, in Boston, MA.
- | Stifel Nicolaus Weisel Healthcare Conference 2012, September 4-7, in Boston, MA.
- | Robert W Baird Health Care Conference, September 5-6, in New York City, NY.

NewLink expects to present at the following oncology and pharmacology meetings:

- | 53rd Annual Meeting of the American Gastroenterological Association in conjunction with Digestive Disease Week at the San Diego Convention Center in San Diego, CA, May 19-22, 2012.
- | 2012 American Society of Clinical Oncology (ASCO) Annual meeting June 1-5, 2012 at the McCormick Place, Chicago, IL.

About NewLink Genetics Corporation

NewLink Genetics Corporation is a biopharmaceutical company focused on discovering, developing and commercializing novel immunotherapeutic products to improve cancer treatment options for patients and physicians. NewLink's portfolio includes biologic and small molecule immunotherapy product candidates intended to treat a wide range of oncology indications. NewLink's product candidates are designed with an objective to harness multiple components of the innate immune system to combat cancer, either as a monotherapy or in combination with current treatment regimens, without incremental toxicity. NewLink's lead product candidate, HyperAcute Pancreas cancer immunotherapy is being studied in a Phase 3 clinical trial in surgically resected pancreatic cancer patients (patient information is available at <http://www.pancreaticcancer-clinicaltrials.com>). This clinical trial is being performed under a Special Protocol Assessment with the U.S. Food and Drug Administration. NewLink and its collaborators have completed patient enrollment for a Phase 1/2 clinical trial evaluating its HyperAcute Lung cancer immunotherapy product candidate for non-small cell lung cancer and a Phase 2 clinical trial for its HyperAcute Melanoma cancer immunotherapy product candidate. NewLink also is developing d-1-methyltryptophan, or D-1MT, a small molecule, orally bioavailable product candidate from NewLink's proprietary indoleamine (2, 3) dioxygenase, or IDO, pathway inhibitor technology. Through NewLink's collaboration with the National Cancer Institute, NewLink is studying D-1MT in various chemotherapy and immunotherapy combinations in two Phase 1B/2 safety and efficacy clinical trials. For more information please visit www.linkp.com.

Cautionary Note Regarding Forward-Looking Statements

This press release contains forward-looking statements of NewLink that involve substantial risks and uncertainties. All statements, other than statements of historical facts, contained in this press release are forward-looking statements, within the meaning of The Private Securities Litigation Reform Act of 1995. The words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "target," "potential," "will," "could," "should," "seek," or the negative of these terms or other similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. These forward-looking statements include, among others, statements about: NewLink's financial guidance for 2012; the timing for completion of enrollment of our Phase 3 clinical trial for our HyperAcute Pancreas cancer immunotherapy; the timing of release of clinical data from ongoing clinical studies; NewLink's future financial performance, results of operations or sufficiency of capital resources to fund its operating requirements; and any other statements other than statements of historical fact. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements that NewLink makes due to a number of important factors, including those risks discussed in "Risk Factors" and elsewhere in NewLink's Annual Report on Form 10-K for the period ended December 31, 2011, in its Quarterly Report on Form 10-Q for the period ended March 31, 2012, and in its other filings with the Securities and Exchange Commission. The forward-looking statements in this press release represent NewLink's views as of the date of this press release. NewLink anticipates that subsequent events and developments will cause its views to change. However, while it may elect to update these forward-looking statements at some point in the future, it specifically disclaims any obligation to do so. You should, therefore, not rely on these forward-looking statements as representing NewLink's views as of any date subsequent to the date of this press release.

NewLink Genetics Corporation
Condensed Consolidated Statements of Operations
(unaudited)
(In thousands, except share and per share amounts)

	<u>Quarter Ended</u>	
	<u>March 31,</u>	<u>March 31,</u>
	<u>2012</u>	<u>2011</u>
Grant revenue	\$ 471	\$ 604
Operating expenses:		
Research and development	3,830	3,180
General and administrative	<u>1,458</u>	<u>1,316</u>
Loss from operations	(4,817)	(3,892)
Other (expense) income, net	<u>(25)</u>	<u>(6)</u>
Net loss	<u>\$ (4,842)</u>	<u>\$ (3,898)</u>
Net loss attributable to NewLink	<u>\$ (4,842)</u>	<u>\$ (3,897)</u>
Net loss per common share, basic and diluted	<u>\$ (0.23)</u>	<u>\$ (1.07)</u>
Weighted average number of common shares outstanding	<u>20,613,146</u>	<u>3,636,044</u>

NewLink Genetics Corporation
Condensed Consolidated Balance Sheets
(unaudited)
(In thousands, except share and per share amounts)

	<u>March 31,</u>	<u>December 31,</u>
	<u>2012</u>	<u>2011</u>
Assets		
Current assets:		
Cash, cash equivalents and certificates of deposit	\$ 35,759	\$ 41,980
Prepaid expenses and other current assets	<u>1,459</u>	<u>808</u>
Total current assets	<u>37,218</u>	<u>42,788</u>
Property and equipment, net	<u>6,229</u>	<u>5,591</u>
Total assets	<u><u>\$ 43,447</u></u>	<u><u>\$ 48,379</u></u>
Liabilities and Equity		
Current liabilities:		
Accounts payable and accrued expenses	\$ 2,029	\$ 3,537
Deferred rent	65	913
Other current liabilities	<u>216</u>	<u>6,214</u>
Total current liabilities	<u>2,310</u>	<u>10,664</u>
Long-term liabilities:		
Royalty obligation payable	6,000	—

Notes payable and obligations under capital leases	885	942
Deferred rent	<u>1,454</u>	<u>—</u>
Total long-term liabilities	<u>8,339</u>	<u>942</u>
Total liabilities	<u>10,649</u>	<u>11,606</u>

Stockholders' equity:

Preferred Stock	—	—
Common stock	207	206
Additional paid-in capital, net	118,909	118,043
Deficit accumulated during the development stage	<u>(86,318)</u>	<u>(81,476)</u>
Total NewLink Genetics stockholders' equity	<u>32,798</u>	<u>36,773</u>
Total equity	<u>32,798</u>	<u>36,773</u>
Commitments	—	—
Total liabilities and equity	<u>\$ 43,447</u>	<u>\$ 48,379</u>

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